

Attorney Docket No.: J6832(C)
Serial No.: 10/800,810
Filed: March 15, 2004
Confirmation No.: 1604

REMARKS

The present amendment is submitted in an earnest effort to advance the case to issue without delay.

The Examiner has acknowledged submittal of a Terminal Disclaimer. This document was said by the Examiner to disclaim the terminal portion of any patent granted on this application that would extend beyond the expiration date of 6730717 and 6770689.

Applicant believes there is an error regarding the Examiner's identification of the Terminal Disclaimer. Our records and that in the PAIR system reflect submittal of a Terminal Disclaimer on March 5, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the following pending application Serial Nos.: 10/767,679; 10/374,300; 10/601,731 and 10/601,856 none of which have matured into a granted patent. The Examiner is requested to review the record to clarify the inconsistency of the statement in the last Office Action.

Claims 1, 3 and 4 were rejected under 35 U.S.C. § 103(a) as unpatentable over Paniccia (Poucher's Perfumes Cosmetics and Soaps 2000) and Jokura et al. (U.S. Patent 5,641,495) and Curtis et al. (U.S. Patent 5,962,018). Applicant traverses this rejection.

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The present invention concerns a method for overcoming in-grown hair. Another name for this affliction is razor bumps or *pseudofolliculitis barbae*. Basis of the problem is that curved hairs grow out and then re-enter the skin like a small splinter, resulting in inflammation and in some instances pustule formation. See Paniccia at page 348, last paragraph. Even though the reference describes the razor bump problem, nothing in the reference suggests a solution. Paniccia does speak about the desirability of reducing irritation caused by shaving nicks and cuts. However, this is not associated with the discussion on razor bumps.

Even were one to subscribe to the Examiner's theory that irritation is the underlying problem to overcoming in-grown hair, it does not follow that lubrication or moisturization would solve this problem. In particular, the Examiner refers to a formulation at page 351 (Formula I) cited for containing glycerol as a moisturizing ingredient.

Applicant reports a clinical study under Example 6 of the specification. Four active materials were evaluated (see Table VII) in a base formula (see Table VI). Cell A employed salicylic acid salt. Results were much inferior to Cells B, C and D. Note that the base formula for all the cells (Table VI) contains 7% glycerin (glycerol). Accordingly, Cell A through the base formula serves as a control experiment. It is evident that 7% glycerin without the further presence of a malonic acid salt does not provide the same level of relief against in-grown hair as does the malonic acid salts. Compare results of treatment with the formula in Cell A versus results in Cell B, C and D. The Examiner's theory that glycerin (glycerol) or moisturizing agents are key to relief of the condition is not substantiated.

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Jokura was introduced for disclosing amine salts of malonic acid in cosmetically acceptable vehicles. These are said to be moisturizers. Of course, malonic acid is only one of numerous dicarboxylic acids mentioned in the reference. See the listing at column 3, lines 31-37. None of the three examples bridging columns 5-8 employ malonic acid or any derivative thereof. These utilize succinic and fumaric acids and salts. The skilled chemist is left with but a single instance of mention to malonic acid or salt.

The Examiner has also emphasized that Jokura reports the dicarboxylic acids/salts as having excellent moisturizing effect yet causing no irritation. See column 1, lines 59-61. A skilled chemist would learn that the dicarboxylic derivatives might be excellent moisturizers without negative effects. However, there is absolutely no teaching that these same dicarboxylic derivatives are anti-irritants. These do not serve as antidotes to remedy an inflammation or irritation problem caused by some other species. In the present invention, the in-grown hairs are the irritation/inflammation agents. Jokura does not state or imply that dicarboxylic derivatives (e.g. malonates) solve inflammations or irritations; they merely would not be likely to aggravate the irritation/inflammation condition.

Curtis was introduced as teaching that therapeutic organic acids are useful for treating skin disorders. A list of 19 disorders beginning with dry skin and ending with calluses are reported as treatable by the therapeutic organic acids. See column 1, lines 22-28. Other treatable conditions are reported in the subsequent paragraphs at page 1 (lines 29-42). Therein included is in-grown hair (*pseudofolliculitis barbae*).

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Curtis specifies that the "therapeutic organic acids" are: "alpha-hydroxy acids, beta-hydroxy acids, di-alpha-hydroxy acids and keto-acids, all of which as a group are commonly referred to as AHAs (alpha-hydroxy acids). See column 2, lines 18-22. Structurally common to all the "therapeutic organic acids" is the presence of a hydroxyl group. Moreover, this hydroxyl group is either one (alpha) or two (beta) carbons distant from the carboxylic acid function.

Malonic acid has no hydroxyl groups. It is neither an alpha-hydroxy nor a beta-hydroxy acid.

Applicant is quite aware that alpha-hydroxy carboxylic acids have been known as effective against the in-grown hair problem. What was very surprising to applicant was that a non-alpha-hydroxy carboxylic acid would have any affect whatsoever on ameliorating this problem. Again attention is drawn to applicant's specification under Example 6. In Table VII the malonic acid salts are compared with a salicylic acid salt. The latter is a beta-hydroxy carboxylic acid (of a type encompassed by Curtis). Applicants have shown that the cell A with salicylate was less effective than the other cells containing malonate salts. Applicant does recognize that salicylate was utilized at 2% while malonate was formulated at 5%. Nonetheless, the most surprising aspect was that the malonates showed even a small amount of activity (no matter what the concentration level).

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The combination of Paniccia in view of Jokura and Curtis would not lead to the present invention. Paniccia as the Examiner agrees does not disclose malonates. The primary reference was cited for suggesting that moisturizers have an ameliorative affect upon the in-grown hair or razor bump problem. Applicant does not read the Paniccia disclosure as teaching this connection. Any mention of moisturizers reducing irritation are connected with damage caused by shaving nicks and cuts. These are not associated with the discussion on razor bumps.

Even arguendo were the Examiner's interpretation correct, it does not simply follow that any moisturizer would solve the in-grown hair or razor bumps problem.

Jokura was cited for teaching that malonates are moisturizers. Even within the context of Jokura, malonates are only mentioned once. There are a number of dicarboxylic acids of greater prominence in this reference, two of which occupy the illustrative Examples. A skilled chemist attempting to select an appropriate moisturizer would not first focus upon malonic acid in the Jokura reference. In fact, the skilled chemist would have no particular interest in any of the dicarboxylic acids of this reference over the multitude of other moisturizer possibilities within the literature. Simply there is nothing special about malonic acid as it appears in this reference.

The Examiner has argued that Jokura teaches the dicarboxylic acids to moisturize without irritation. The "without irritation" does not imply that they are anti-irritants. There is no suggestion in this reference that the disclosed dicarboxylic acids would act against an irritated or inflamed skin condition. At best, they are taught as not aggravating the situation. The skilled chemist would not have any appreciation that

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dicarboxylic acids, much less malonates, could be active against the in-grown hair inflammation/irritation problem.

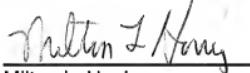
Curtis is concerned with "therapeutic organic acids". These are described as alpha-hydroxy or beta-hydroxy carboxylic acids. Malonates are not hydroxy acids. The skilled chemist would not select a non-hydroxy acid (e.g. malonic) based on any teachings in this reference.

In summary, the Examiner's suppositions for the combination of references is misplaced. Paniccia does not teach moisturizers as solving the in-grown hair problem. Therefore, the Jokura moisturizers are irrelevant to solving applicant's problem. Dicarboxylic acids such as malonates may be skin friendly but certainly are not anti-irritants. The Examiner is incorrect in viewing Jokura as teaching anti-irritant actives. And finally there is Curtis. This reference is to alpha- or beta- hydroxycarboxylic acids. The malonates are not of that description. There is nothing that the skilled chemist would glean from the combination of references to arrive at applicant's solution of the in-grown hair (razor bumps) or *pseudofolliculitis barbae* problem. For these reasons use of malonates in treating the aforementioned skin condition is non-obvious to those of skill in the art.

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In view of the foregoing comments, applicant requests the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,


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